

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
**Rosanne M. Crooke, Et. al.**

Confirmation No.: **6394**

Application No.: **10/712,795**

Group Art Unit: **1633**

Filing Date: **November 13, 2003**

Examiner: **Janet L. Epps-Ford**

For: **ANTISENSE MODULATION OF APOLIPOPROTEIN B EXPRESSION**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Examiner Epps-Ford:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing references to be considered by the Examiner. Also enclosed are foreign patent references and non-patent literature as listed on the Supplemental Information Disclosure Statement.

Included herewith is the fee set forth under 37 C.F.R. § 1.17(p). If an additional fee is due, the Commissioner is hereby authorized to charge Deposit Account No 500252 referencing case number DOC-0216US.

Applicants thank the Examiner for agreeing to consider the references listed on the Supplemental Information Disclosure Statement. For the Examiner's convenience, Applicants provide herewith an additional Listing of the References, beginning on page 2 of this paper.

### LISTING OF REFERENCES

For the Examiner's consideration, listed below are references that were cited in (1) an Office Action of a commonly assigned U.S. Application; (2) an International Search Report of a PCT counterpart of the instant application; (3) a European Search Report of a European counterpart of the instant application, or (4) the background of the instant application.

- References included on "Notice of References Cited" in connection with U.S. Application Serial No. 09/920,033 ('033; currently pending)
  - Office Action mailed January 13, 2004 (Examiner Epps-Ford).
    - One of three references cited by the Examiner in the '033 application in support of a rejection under 35 U.S.C. § 103(a) (the remaining references cited in support of that rejection are already of record in the instant application).
      - *Agrawal, S. et al., Mol. Med. Today (2000)*
  - Office Action mailed January 19, 2005 (Examiner Epps-Ford).
    - One of several references cited by the Examiner in the '033 application in support of a rejection under 35 U.S.C. 103(a) (the remaining references cited in support of that rejection are already of record in the instant application).
      - *Rossi, J.J., et al., Methods Enzym. (1993)*
  - Office Action mailed June 26, 2006 (Examiner Epps-Ford).
    - Four of six references cited by the Examiner in the '033 application in support of a rejection under 35 U.S.C. 103(a) (remaining references cited in support of that rejection are already of record in the instant application).
      - *US 6,512,161, Rouy et al., published 01/28/2003*
        - Note: The PCT publication counterpart to US 6,512,161, WO 99/35241, is of record in the instant application (cited by Applicants on a PTO/SB/08 Equivalent dated March 31, 2006 and initialed by Examiner Epps-Ford, indicating that the reference was considered).
      - *Huang, L.-S., et al., J. Biol. Chem (1969)*
        - Cited for disclosure of GenBank Accession number NM\_000384.1.
      - *US 2002/0068708, Wengel et al., published 06/06/2002*
      - *Agrawal, S. et al., Mol. Med. Today (2000); listed above*
    - One of two references cited by the Examiner in the '033 application in support of a rejection under 35 U.S.C. 103(a) (the other reference is already of record in the instant application).
      - *US 2002/0068708, Wengel et al., published 06/06/2002*
    - Cited by the Examiner in the '033 application in support of a rejection under 35 U.S.C. § 102(b).
      - *WO 00/00504, Baker et al., published 01/06/2000*

- The Examiner asserted that SEQ ID NO: 24 of Baker et al. is 88.9% complementary to nucleotides 177 through 194 of the human apolipoprotein B mRNA as set forth in GenBank Accession No. NM\_000384.1.
- References included on “Notice of References Cited” in connection with U.S. **Application Serial No. 10/147,196** (‘196; currently pending)
  - **Office Action** mailed July 11, 2003 (Examiner Epps-Ford).
    - Three references of four references cited by the Examiner in the ‘196 application in support of a rejection under 35 U.S.C. § 112, enablement (the remaining reference is already of record in the instant application).
      - *Crooke, S.T., Antisense Research and Application (1998)*
      - *Jen, K.-Y., et al., Stem Cells (2000)*
      - *Ma, D.D.F. et al., Biotech. Ann. Rev. (2000)*
- References included on “Notice of References Cited” in connection with U.S. **Application Serial No. 10/920,612** (‘612; currently pending), which is a continuation of the present application.
  - **Office Action** mailed March 28, 2007 (Examiner Epps-Ford)
    - Two references cited in the ‘612 application in support of a rejection under 35 U.S.C. § 103(a).
      - *WO 03/074723, Dhallan, published 09/12/2003*
      - *Latorra, D., et al., Hum. Mutat. (2003)*
- Reference included on “Notice of References Cited” in connection with U.S. **Application Serial No. 11/200,710** (‘710; currently pending).
  - **Office Action** mailed May 17, 2007 (Examiner Shin)
    - One of two references cited by Examiner in the ‘710 application in support of rejection under 35 U.S.C. § 103(a) (the other reference is PCT/US/03/15493, to which the instant application claims priority).
      - *Skrapari, L. et al., Diabetic Med. (2001)*
- Reference cited in ‘**Background of the Invention**’ of U.S. **Application Serial No. 10/712,795** (instant application).
  - *Nowak-Gottl, U. et al., Pediatrics (1997)*
    - A clinical survey suggesting that increased concentrations of Lp(a) play an important role in childhood thrombosis.
- Cited in the **International Search Report** issued August 31, 2004 in connection with **PCT/US03/036411**, which is the PCT counterpart of the instant application.
  - *US 5,801,154, Baracchini et al., Published 09/01/1998*
    - A patent entitled “Antisense Oligonucleotide Modulation of Multidrug Resistance-Associated Protein.”
- References cited in a **Partial Supplementary European Search Report** issued 8/16/2006, in connection with **European Application No. 03789763.4**, the European counterpart of the instant application.
  - *WO 03/011887, Crooke et al., Published 02/13/2003*
    - WO 03/011887 claims priority to U.S. Patent Application Serial Nos 09/920,033 and 10/147,196, and contains subject matter related to that found in US Patent Application Serial Nos 09/920,033 and 10/147,196.

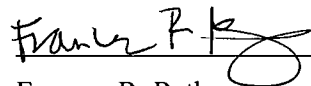
**DOCKET NO.:** DOC-0216US (ISIS.003CP1)  
**Application No.:** 10/712,795

**PATENT**

- *EMBL Accession No. L27195, January 6, 1994*
  - Described as “Dog primer for STS 610, 3' end, sequence tagged site.”
- *Graham, M.J. et al., AHA Abstracts, published 11/5/2002*

Respectfully submitted,

Date: July 9, 2007



Frances R. Putkey  
Agent for Applicant  
Registration No. 57, 257

Isis Pharmaceuticals, Inc.  
Phone 760.603.2710  
Facsimile 760.603.3820

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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|-------|---|----|---|
| Sheet | 1 | of | 2 |
|-------|---|----|---|

**Complete if Known**

|                               |                    |
|-------------------------------|--------------------|
| <i>Application Number</i>     | 10/712,795         |
| <i>Filing Date</i>            | 11/13/2003         |
| <i>First Named Inventor</i>   | Rosanne M. Crooke  |
| <i>Art Unit</i>               | 1633               |
| <i>Examiner Name</i>          | Janet L. Epps-Ford |
| <i>Attorney Docket Number</i> | DOC-0216US         |

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |                        | Application Number       | 10/712,795         |
|   |                        | Filing Date              | 11/13/2003         |
|   |                        | First Named Inventor     | Rosanne M. Crooke  |
|   |                        | Art Unit                 | 1633               |
|   |                        | Examiner Name            | Janet L. Epps-Ford |
| Sheet 2 of 2  | Attorney Docket Number | DOC-0216US               |                    |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials *             | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | DK                    | AGRAWAL, S. et al., "Antisense therapeutics: is it as simple as complementary base recognition?" <i>Mol. Med. Today</i> (2000) 6:72-81.   |                |
|                                 | DL                    | CROOKE, S. T., "Basic Principles of Antisense Therapeutics," <i>Antisense Research and Application</i> (1998) Springer-Verlag Press, Berlin, pp 1-50.   |                |
|                                 | DM                    | EMBL Accession No. L27195, January 6, 1994.   |                |
|                                 | DN                    | GRAHAM, M. J. et al., "Inhibition of ApoB-100 as a Therapeutic Strategy for the Treatment of Hyperlipidemias," <i>AHA Abstracts</i> (2002).   |                |
|                                 | DO                    | HUANG, L.-S. et al., "Hypobetalipoproteinemia Due to an Apolipoprotein B Gene Exon 21 Deletion Derived by Alu-Alu Recombination," <i>J. Biol. Chem.</i> (1969) 264(19):11394-11400.   |                |
|                                 | DP                    | JEN, K.-Y. et al., "Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies," <i>Stem Cells</i> (2000) 18:307-319.   |                |
|                                 | DQ                    | LATORRA, D. et al., "Enhanced Allele-Specific PCR Discrimination in SNP Genotyping Using 3' Locked Nucleic Acid (LNA) Primers," <i>Hum. Mutat.</i> (2003) 22:79-85.   |                |
|                                 | DR                    | MA, D. D. F. et al., "Synthetic oligonucleotides as therapeutics: the coming of age," <i>Biotech. Ann. Rev.</i> (2000) 5:155-196.   |                |
|                                 | DS                    | NOWAK-GÖTTL, U. et al., "Lipoprotein (a): Its Role in Childhood Thromboembolism," <i>Pediatrics</i> (1997) 99(6):1-3.   |                |
|                                 | DT                    | ROSSI, J. J. et al., "Introductory Remarks on the General Application of Antisense RNAs and Ribozymes," <i>Methods Enzym.</i> (1993) 5:1-5.   |                |
|                                 | DU                    | SKRAPARI, L. et al., "Glibenclamide improves postprandial hypertriglyceridaemia in Type 2 diabetic patients by reducing chylomicrons but not the very low-density lipoprotein subfraction levels," <i>Diabetic Med.</i> (2001) 18:781-785.                      |                |
|                                 | DV                    | TANAKA, M et al. "Regulation of Apolipoprotein B Production and Secretion in Response to the Change of Intracellular Cholesteryl Ester Contents in Rabbit Hepatocytes," <i>J. Biol. Chem.</i> (1993) 268(17):12713-12718.                                       |                |
|                                 |                       |   |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.